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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,500	12/02/2004	Juan Luis Hancke Orozco	Herbal Powers	4925

22925 7590 08/01/2006

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EXAMINER
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RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/516,500	HANCKE OROZCO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Niloofer Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 53-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 53-73 are pending and claims 1-52 are cancelled.

2. ***Priority***

This application is a 371 of PCT/EP04/05516, filed on 05/21/2004, which claims the priority of CHILE 178-2004, filed on 02/03/2004.

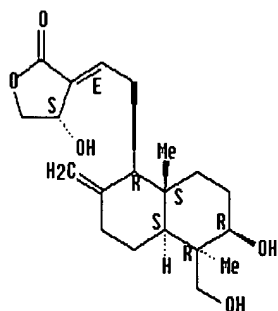
3. The rejection of claims 53-73 under 35 U.S.C. 112, second paragraph for “receptor?, NF?B., interferon?, 5,ha” is withdrawn in view of the applicant’s amendment and argument.

4. The rejection of claim 73 under 35 U.S.C. 112, first paragraph for “Andrographis paniculata” is maintained for reason of record. Applicants argue that this is not a “scope of enablement rejection”. It is the examiner’s position that Andrographis paniculata grown just anywhere everywhere on this planet may or may not have the compounds necessary to treat Syndrome X. Does this extract of this plant, grown under any and all conditions, treat Syndrome X? This is a scope of enablement rejection.

5. The rejection of claims 53-73 under 35 U.S.C. 112, first paragraph for “diagnosing in a patient a disease selected from the group consisting of Alzheimer’s disease; Acquired immune deficiency syndrome; autoimmune disease; a disease; Syndrome X” is maintained for reason of record. Applicants argue that the claims are not drawn to “a method of diagnosing a patient” but are drawn to a method of treating a patient. Further, applicant argues that the claims do not purport to cover “any and

all known or unknown diseases.” It is the examiner’s position that the claims are drawn to “ a method of diagnosing in a patient a disease”. The claims are not drawn to “method of treating a disease”.

6. The rejection of claims 53-73 under 35 U.S.C. 102(b) over Boggs et al., US 5,883,074, Babish et al., US 2002/0068098, Panossian et al. Phytomedicine, Vol. 9, pages 598-605, Wheelock et al., US 5,833,994, Babish et al., US 2002/0077350, Wheelock et al., US 6,140,063, Babish et al., WO 96/17605, Wheelock et al. WO 98/30213, Nanduri et al., US 6,410,590, Nanduri et al., US 6,486,196, and Nanduri et al., US 2002/0016324 is maintained for reason of record. Applicants argue that these references have different structure than the instant compounds. It is the examiner’s position that Andrographolide is well known to be the structure as



RN 5508-58-7 REGISTRY

CN 2(3H)-Furanone, 3-[2-[(1R,4aS,5R,6R,8aS)-decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]dihydro-4-hydroxy-, (3E,4S)- (9CI)

OTHER CA INDEX NAMES:

**CN** 2(3H)-Furanone, 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]dihydro-4-hydroxy-,

**CN** 5.beta.,9.beta.H,10.alpha.-Labda-8(20),12-dien-16-oic acid,  
3.alpha.,14,15,18-tetrahydroxy-, .gamma.-lactone (7CI)

**CN** Andrographis (6CI)

OTHER NAMES:

**CN** Andrographolid

**CN** Andrographolide. It is the same as the instantly claimed compound.

All the references include Andrographolide as the common name. It is noted that Babish et al., 2002/0077350, and US 2002/0068098 have incorrect structure for Andrographolide. But Andrographolide is well known to be the structure as the above. Boggs et al., US 5,883,074 has Andrographolide on sheet 13, the last compound # 512, which is Andrographolide correctly. Babish et al., US 2002/0068098 has Andrographolide on sheet 2, compound # B3, which is depicted in Babish et al. Andrographolide has shown above is well known. Panossian et al., Phytomedicine, Vol. 9, pages 598-605 has Andrographolide on page 608, which is depicted in Panossian et al. Andrographolide has shown above is well known. Wheelock et al., US 5,833,994 has Andrographolide on column 21, lines 49-52, which is depicted in Wheelock et al.

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Andrographolide has shown above is well known. Babish et al., US 2002/0077350 has Andrographolide on sheet 2, compound C3, which is depicted in Babish et al. Andrographolide has shown above is well known. Wheelock et al., US 6,140,063 has Andrographolide on column 22, lines 35-38, which is depicted in Babish et al. Andrographolide has shown above is well known. Babish et al., WO 96/17605 has Andrographolide on page 16, lines 15-16. Andrographolide has shown above is well known. Wheelock et al., WO 98/30213 has Andrographolide on page 32, Example 8, lines 5-7. Andrographolide has shown above is well known. Nanduri et al., US 6,410,590 has Andrographolide on column 8, formula II, which is Andrographolide correctly. Nanduri et al., US 6,486,196 has Andrographolide on column 2, formula II, which is Andrographolide correctly.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the

mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

07/20 /2006

NR



D MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625